

### **REMARKS**

The present application is directed to a method of enhancing expression of a desired protein at mucosal effector sites of a mammal by placing a nucleotide sequence encoding the protein to be expressed under the control of a promoter having the nucleotide sequence SEQ ID NO: 2 in a recombinant gut-colonizing microorganism, administering the microorganism to the mammal, and causing expression of the desired protein in mucosal cells. Such microorganisms are useful for protecting humans against potential biological warfare agents such as plague.

Following entry of this amendment Claims 1, 23, 25-32 will be pending. Claims 1, 23, 25, 26, 28, 29, and 31 are amended. Claims 2-22 and 24 are cancelled without prejudice. No new matter is added and support for the amendments can be found throughout the specification.

#### ***Informalities-Specification***

In the Office Action mailed August 8, 2006, the Examiner objected to the specification for failing to provide proper antecedent basis for the claimed subject matter.

Applicants have amended page 4 of the specification as suggested by the Examiner. Accordingly, applicants respectfully request withdrawal of the Examiner's objection to the specification.

#### ***Claim rejections under 35 U.S.C. § 112, first paragraph***

In the Office Action mailed August 8, 2006, the Examiner rejected Claims 1, 23 and 24 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claims 1 and 23 have been amended to clarify that the promoter sequence and the nucleotide sequence encoding the desired protein are administered to a mammal in a

recombinant gut-colonizing microorganism. Support for the claim amendments can be found on at least page 4, lines 22-28 and page 4, lines 30-31 of the instant application. Claim 24 has been cancelled. Accordingly, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

***Claim rejections under 35 U.S.C. § 112, second paragraph***

In the August 8, 2006 Office Action, the Examiner rejected Claims 1 and 23-32 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully submit that the amendments to the claims overcome the rejection.

With regard to item “(a)” in this section of the Office Action, Claim 1 has been amended to clarify that the steps of placing the nucleotide sequence encoding the protein under the control of the recited promoter and administration to mucosal cells occurs *in vivo* because the recombinant gut-colonizing microorganism containing the nucleotide sequence is administered to a mammal. Applicants submit that it is clear from the amended claims that the mucosal cells are part of the mammal and that the desired protein is administered to the mucosal cells via the microorganism. Support for the claim amendments can be found on at least page 4, lines 22-28 and page 4, lines 30-31 of the instant application.

With regard to item “(b)” in this section of the Office Action, the Examiner concluded that it is unclear how many steps of administration are involved in the method of Claim 23 and how many products are administered. As discussed above, Claim 1 has been amended to clarify that only one step of administration to the mammal is needed in the method, and that step is administration of the microorganism to the mammal.

With regard to item “(c)” in this section of the Office Action, applicants respectfully submit that Claim 24 has been cancelled without prejudice, thus rendering the rejection of Claim 24 moot.

With regard to item “(d)” in this section of the Office Action, Claim 29 has been amended to clarify that the protective immune response against *Yersinia pestis* is a result of an immune response induced by the desired protein of Claim 23.

With regard to item “(e)” in this section of the Office Action, the Examiner rejected Claims 31 and 32 as being indefinite on the basis that it was not clear to whom or what the composition comprising the recombinant gut-colonizing microorganism is administered. Applicants respectfully submit that the amendments to Claim 1 address this issue. Specifically, Claim 1 has been amended to clarify that the recombinant gut-colonizing microorganism is administered to a mammal.

With regard to item “(f)” in this section of the Office Action, applicants respectfully submit that the amendment to Claim 1, as described above, clarifies the claimed subject matter and obviates the Examiner’s rejection of dependent Claims 23, and 25-32.

Applicants respectfully submit that the amendments to the claims as provided herein overcome rejections (a)-(f) as raised by the Examiner. Accordingly, applicants respectfully request withdrawal of the Examiner’s rejection under 35 U.S.C. §112, second paragraph.

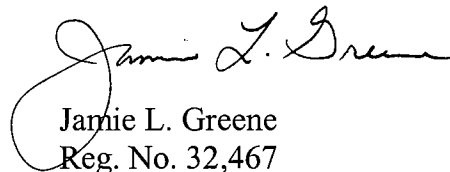
### **CONCLUSION**

The foregoing is submitted as a full and complete Response to the Final Office Action mailed on August 8, 2006. For at least the reasons given above, applicants respectfully submit that the pending claims are definite. Accordingly, applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited.

If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application that may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

No additional fees are believed due; however the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account number 11-0855.

Respectfully submitted,



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